



MONITORING OF ERYTHROPOIESIS STIMULATING AGENTS (ESA) LOCAL ENHANCED SERVICE SPECIFICATION

Version Control		
Version	Date Amended	Summary of amendments
ESA LES amended Nov 2012	April 2022	Level 1 & 2 fees amended. Termination and GMPI info added
Erythropoietins Stimulating Agents LES Specification, <i>amended April 2022</i>	May 2023	Fees updated
ESA LES SPEC 2023-24	June 2023	Justified Claims wording added. Termination and GMPI information moved to end of document

Introduction

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient all of which are beyond the scope of essential service. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

Background

This Local Enhanced Service is subject to the provisions of the BroTaf Localities Drugs and Therapeutic Committee for Erythropoiesis Stimulating Agents (ESA) and is designed to ensure appropriate therapy for patients with Anaemia and Chronic Kidney disease (CKD) including those on dialysis.

To ensure appropriate monitoring is carried out in respect of patients in receipt of Erythropoiesis Stimulating Agents (ESA), whether self administered, administered by GP practice or administered by a third party (inc. District Nurses), including;

- a) Pre-Dialysis Patients
- b) Peritoneal Dialysis Patients
- c) Transplant Patients
- d) Haemodialysis patients, including those on Home Haemodialysis,

Aims

This scheme is designed to be one in which:

- a) Patients initiated by the nephrology department are monitored during the correction (as defined in monitoring pathway) and maintenance phases of ESA treatment
- b) The service to the patient is convenient
- c) The use of resources by the National Health Service is efficient

Service Outline

This Local Enhanced Service will fund:

- a) **a primary care based monitoring service** in respect of the following specified drugs:
 - i) Erythropoietin (Epoetin Alfa & Beta)
 - ii) Darbepoetin Alfa

This list of eligible drugs may be updated in the light of formulary application decisions

- b) **A register.** Practices should be able to produce and maintain an up-date register of patients, indicating name, date of birth.
- c) **Call and recall.** To ensure that systematic call and recall of patients on this register is taking place either in a hospital or general practice setting.
- d) **Continuing information for patients.** To ensure that all patients (and/or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information
- e) **Professional links.** To work together with other professional when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained
- f) **Referral policies.** Where appropriate to refer patients promptly to other necessary services and to the relevant support agencies using local agreed guidelines where these exist
- g) **Record keeping.** To maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. hospital admission, death of which the practice has been notified
- h) **Training.** Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so
- i) **Prescribing** of appropriate oral iron supplementation for patients falling outside the specified therapeutic range

Components of the service (frequency of monitoring)

- a) **Blood Pressure** monitoring to be recorded for each patient every 4 weeks or as advised by specialist nephrology service during the correction phase. Blood pressure monitoring will be required less frequently during the maintenance phase and may not be required at all – to be advised by specialist nephrology service. During the first 3 months of the initiating period secondary care will be accountable / responsible for analysing and responding to BP; this accountability/responsibility will then switch to primary care once patient is stable. Noncompliant patients may be removed from ESA therapy by Cardiff & Vale Nephrology department.
- b) **Haemoglobin monitoring.** Blood sampling to be undertaken by practices monthly or as advised by specialist nephrology service for each patient during the correction phase and every 2 to 3 months in the maintenance phase (Hb stable in target range and ESA dose stable). The aim of ESA therapy for the majority of patients is to achieve and maintain Hb levels
- c) between 10.5 and 12.5 g/dl in accordance with recommendations from NICE. Secondary Care will be accountable/responsible for analysing and responding to blood results. Non compliant patients may be removed from ESA therapy by the Cardiff and Vale Nephrology department.

Patient	Primary Care	Secondary Care
Blood Monitoring Correction Phase & Stable Patients		
Pt is given 12 blood forms with pre-printed lab labels from secondary care.	Blood monitoring 1 x month. Results are sent directly to secondary care.	Secondary care is accountable / responsible for analysing and acting on blood results.
Blood Pressure Monitoring Correction Phase		
During the first 3 months of initiation BP must be recorded 1 x month	BP is taken by practice nurse/ District Nurse, result is phoned through to secondary care	BP is recorded in patient's record. Secondary Care is accountable / responsible for analysing BP
Blood Pressure Monitoring Patient Stable		
BP must be recorded every 2-3 months	BP is taken by practice nurse / District Nurse; results are recorded in patient's record book (similar to INR recording book). Any changes to BP, responsibility lies with GP to investigate further.	If patient DNA's for monitoring secondary care will be responsible for calling patient.
Change to dose Standard letter will be sent to GP to step up monitoring from Secondary Care		

Patient must attend surgery once every month for three months	BP is taken by practice nurse, result is phoned through to secondary care Patients will be treated / regarded as newly initiated at this point	BP is recorded in patient's record. Secondary Care is responsible for analysing BP
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Untoward events

It is a condition of participation in this LES that practitioners will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her to the PCO clinical governance lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition.

Accreditation

Those doctors who have previously provided services similar to the proposed enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

Cost

In 2023/24 each practice contracted to provide this service will receive:

Level 1	Practice monitors patient blood pressure, Trust employed phlebotomist samples blood	£112.94
Level 2	Practice monitors patient blood pressure, Practice funded phlebotomist samples blood	£124.23

Claims

Practices must ensure all claims are submitted via FPPS within 6 months from the end of the quarter in which the service was delivered. Practices will be paid quarterly in arrears and will be subject to post payment verification (PPV).

Termination Period

Should the practice wish to cease providing the Enhanced Service, it will be required to provide 3 months' notice in writing to the Health Board. Should the practice wish to suspend providing the Enhanced Service it should contact the Health Board for guidance prior to any action being taken.

If, for any reason, a practice terminates/suspends the Enhanced Service and, if claims have been made during the current financial year, any reporting/auditing requirements outlined in the specification must be submitted

upon request.

General Medical Practice Indemnity

This Enhanced Service is covered by the scheme for General Medical Practice Indemnity (GMPI) which falls under the GMS Contract Wales.

This scheme relates to potential or actual clinical negligence claims arising from incidents on or after 1 April 2019, and captures all General Medical Practice (GP practice) staff undertaking NHS 'primary medical services' as defined in The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019

The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019, sets out the scope of the scheme, namely "primary medical services" which are defined as health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the National Health Service Wales Act 2006:

- (a) section 41(2) (primary medical services);
- (b) section 42(1) (general medical services contracts);
- (c) section 50 (arrangements by Local Health Boards for the provision of primary medical services).

The GMPI will include clinical negligence liabilities for NHS work arising from the activities of all GP practice staff, including: GP partners; salaried GPs; locum GPs, if on the All Wales Locum Register; Practice Pharmacists; Practice Nurses; Practice Healthcare assistants; and any other member of staff providing clinical services. GP trainees and trainee nursing students delivering general medical services will also be covered. The GMPI will also cover any healthcare professionals providing the delivery of NHS Primary Care through Primary Care cluster arrangements and any vicarious liability to practices where a cluster-based health professional is providing direct care to the practice's registered patients.

GP Locums who are registered with and working to the terms of the All Wales Locum Register (AWLT) for Wales have access to the scheme for GMPI.